REMARKS

Applicant has acknowledged that this application has been examined pursuant to a request for continued examination under 37 CFR 1.114. Claims 4, 11, 34, 37-38 and 41 are currently acknowledged to be under examination. Claims 4 and 34 are now dependent upon claim 11.

The rejection of claims 4, 11, 34, 37-38 and 41 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is respectfully traversed.

Claims 11 and 41 have been amended and claims 4 and 34 now depend from claim 11. Claim 38 depends from claim 37 and claims 37 and 41 are similar in objective and methodology to claim 11. In the amended version of claims 11, 27 and 41, it is now clear that the probe antibody in step (1) is limited to a probe monoclonal antibody and that the method of each claim consists of three steps, with steps 1 and 2 involving treating a sample comprising HCV or HBV with a treatment solution containing (a) an ionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant, a nonionic surfactant an a protein denaturant and then inactivating viral particles and antibody in the sample. In the third step (3) the treated sample containing the treatment solution is measured by an immunoassay using a probe monoclonal antibody.

More specifically, in the first and second steps a treating solution and a sample are mixed so that HCV or HBV and endogenous antibodies in the mixture are destroyed and inactivated.

In the third step, the mixture is added to a reaction buffer. In other words, the mixture comprising the treated sample and treating solution is diluted with a reaction buffer, and reacted with a captured antibody so as to assay the samples.

It is now clear from the amended claims that the treating solution in step (1) is diluted in step (3) using a reaction buffer when subjecting the sample to an immunoassay. Therefore, the concentration of the treating solution in step (1) is not

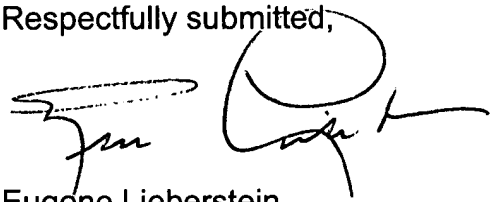
identical to that in the step (3). In addition, the endogenous antibodies inactivated in the step (1) are polyclinic antibodies. On the other hand the probe antibody in the step (3) is a monoclonal antibody. Therefore, the endogenous antibodies are inactivated in the step (1) with the non-diluted treating solution, while the monoclonal antibody in the step (3) is not inactivated with diluted treating solution.

Accordingly, based on the amendments to the claims, the rejection of claims 4, 11, 34, 37-38 and 41 under 35 USC 112, first paragraph, should now be withdrawn. The same is true for the rejection of the claims under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this regard, claims 4, 34 and 38 have been amended to depend properly from a parent claim.

Should the Examiner still find the claims to be indefinite, the Examiner is requested to telephone applicant to facilitate a further amendment without the necessity for nit-picking the interpretation of wording in the claims.

Reconsideration and allowance of claims 4, 11, 34, 37-38 and 41 is respectfully solicited.

Respectfully submitted,



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Date: June 30, 2004

AMENDMENT TO THE CLAIMS

Claims 1-3 (Cancelled)

Claim 4. (Currently Amended) The method according to claim ~~31~~ 11, wherein said treatment solution further contains urea, an imidazole ring-containing compound or an indole ring-containing compound.

Claims 5-10 (Cancelled)

Claim 11. (Currently Amended) A method for detecting a hepatitis C virus (HCV) or hepatitis B virus (HBV) in a sample by obtaining a sample suitable for detection of virus by a probe monoclonal antibody, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution containing (a) an anionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant, a nonionic surfactant and a protein denaturant;

(2) obtaining a treated sample in which the virus particle is disrupted, the virus antigen is exposed or released; and antibodies against the virus antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and

(3) ~~subjecting~~ adding the treated sample containing treatment solution to reaction buffer and detecting the virus antigen by ~~to an~~ immunoassay using the probe monoclonal antibody ~~in the presence of treatment solution~~.

Claim 12. (Withdrawn) A virus assay method, characterized by using a sample treating method according to any one of claims 1 to 10 and reacting it with a probe which specifically recognizes a virus antigen, for detection or quantization of the presence of the virus antigen.

Claims 13-33 (Cancelled)

Claim 34. (Currently Amended) The method according to claim ~~32~~ 11, wherein said treatment solution further contains urea.

Claims 35 and 36 (Cancelled)

Claim 37. (Currently Amended) A method for detecting a hepatitis C virus (HCV) or a hepatitis B virus (HBV) in a sample by obtaining a sample suitable for detection of virus by a probe monoclonal antibody, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphoteric surfactant, and (c) an agent selected from the group consisting of a nonionic surfactant and a protein denaturant, wherein the denaturing effect of the anionic surfactant (a) to the probe monoclonal antibody is reduced by the amphoteric surfactant (b) and the agent (c);

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and

(3) subjecting the sample containing treatment solution diluted with reaction buffer to an immunoassay using ~~a~~ the probe monoclonal antibody ~~in the presence of treatment solution~~ for detecting the viral antigens.

Claim 38. (Currently Amended) The method according to claim ~~33~~ 37, wherein said treatment solution further contains urea.

Claims 39 and 40 (Cancelled)

41. (Currently Amended) A method for detecting a hepatitis C virus (HCV) or hepatitis B virus (HBV) in a sample by obtaining a sample suitable for detection of virus by a probe monoclonal antibody comprising the steps of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphoteric surfactant, (c) a nonionic

surfactant and (d) a protein denaturant; wherein the denaturing effect of the anionic surfactant (a) to the probe monoclonal antibody is reduced by the amphoteric surfactant (b), the nonionic surfactant (c) and the protein denaturant (d);

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and

(3) subjecting the sample containing treatment solution diluted with reaction buffer to an immunoassay using a probe monoclonal antibody ~~in the presence of treatment solution~~ for detecting the viral antigen.